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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,112

12/23/2004

Ole Kaae Hansen

P70305US0

9507

136 7590 02/06/2007

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on 8 November 2006 with the amendment of claims 1, 2 and 5.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 2 and 4-8 are under examination.**

### ***Election/Restrictions***

This application contains claims 3 and 9-20 are drawn to an invention nonelected with traverse in "Response to Election / Restriction Filed" filed on 30 June 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Please replace "butter cake meal" with a more appropriate term that is found within the specification. Newly applied as necessitated by amendment.

***Claim Objections***

Claim 1 is objected to because of the following informalities: "Butyrospermum parkii" must be italicized. Appropriate correction is required. Newly applied as necessitated by amendment.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide prior support or antecedent basis for the language "butter cake meal" (See claim 1, lines 2 and 5) and failing to comply with the written description requirement. Newly applied as necessitated by amendment.

The claim as set forth in the amendment filed 30 June 2006 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the instant case, the original Claim 1 did not disclose butter cake meal, wherein Applicant claimed, as Claim 1, "A method of preparing an aqueous extract comprising saponins on basis of waste product from a shea butter tree, said method comprising the following steps: (i) mixing one part waste product with 4-30 parts of water; (ii) incubating the mixture formed in step (i) under alkaline conditions (pH>7); and (iii) recovering an aqueous extract comprising

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saponins by removing solids from the alkaline mixture formed in step (iii)". In the amended Claim 1, Applicant claims, "A method of preparing an aqueous extract of butter cake meal from a shea butter tree (*Butyrospermum parkii*), enriched in saponins, said method comprising the following steps: (i) mixing one part by weight of butter cake meal with 4-30 parts by weight of water to form an aqueous suspension;

(ii) adding a sufficient quantity of alkali to the aqueous suspension to create alkaline conditions;

(iii) incubating the alkaline aqueous suspension formed to produce an alkaline aqueous extract enriched in saponins;

(iv) separating the alkaline aqueous extract from the butter cake meal; and

(v) isolating the alkaline aqueous extract enriched in saponins", thereby introducing "butter cake meal", which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept for butter cake meal. There is only one exemplified instance of a waste product from shea butter tree, which are "press cake" and "extracted residue (meal)" (See Pre-Grant Publication, paragraph 0011). This is not sufficient support for the new genus: "butter cake meal". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "butter cake meal from a shea butter tree (*Butyrospermum parkii*)," because it is unclear as to what "butter cake meal" is and because it is unclear as to what Applicant means by "butter cake meal from a shea butter tree". Does Applicant mean meal or press cake extracted from shea butter tree or does Applicant mean something else? The phrase "butter cake meal from a shea butter tree (*Butyrospermum parkii*)," should be rewritten

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to better indicate what the "butter cake meal" is (and also to be in compliance) and also should indicate that the "butter cake meal" (or appropriate alternative) is extracted or obtained from shea butter tree. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 102***

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 8 November 2006, with respect to the rejection(s) of claim(s) 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by Oura et al. (A\*, US 4,229,483), as evidenced by Noller (U\*, Ann Rev Biochem. 1945; 14: 383-406) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 U.S.C. 103(a) as being unpatentable over Oura et al. (A\*, US 4,229,483), in view of Noller (U\*, Ann Rev Biochem. 1945; 14: 383-406) and Vogel et al. (V\*, "Fermentation and Biochemical Engineering Handbook-Principles, Process Design and Equipment (2<sup>nd</sup> Edition)"). Please note that this rejection is withdrawn simply because Oura does not expressly teach a separation step, however, Oura teaches that the coloring composition may be in the form of a powder, pellets, a slurry, an emulsion, an aqueous suspension or the like (See column 4, lines 46-54) and also teaches that solids may be separated from a liquid phase (See column 7, Example 32 and column 8, Example 33).

***Claim Rejections - 35 USC § 103***

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oura et al. (A\*, US 4,229,483), in view of Noller (U\*, Ann Rev Biochem. 1945; 14: 383-406) and Vogel et al. (V\*, "Fermentation and Biochemical Engineering Handbook- Principles, Process Design and Equipment (2<sup>nd</sup> Edition)").

Oura teaches a method of preparing an aqueous extract of fine shea nut meal (please note that shea nut meal is a saponin-containing waste product from a shea butter tree and that the shea nut meal is filtered and ground prior to extraction, See column 2, lines 48-51 and lines 55-66) comprising washing the shea nut meal with water, wherein the amount of water is more than 2.5 times as much as volume of the shea nut meal (See column 3, lines 22-24), mixing the shea nut meal with a 10-99% (w/v) aqueous ethanol solution, whereby the alcohol solution may be used in an amount of 0.05 to 5 times as much as the volume of shea nut meal (See column 3, lines 29-30 and 33-35) in the presence of an alkali, wherein the alkali is used in the form of an aqueous solution (See column 3, lines 59-68 and continued into column 4, lines 1-8), which reads on buffer, at a pH of 7.15 or 7.41 (See column 6, table 2) and the solids can be removed by filtration from a liquid medium (See column 7, Example 32). Oura does not expressly teach that the aqueous extract contains saponins, however, saponins are inherent to shea nut press cake (See Noller, page 385), which is synonymous with shea nut meal. Oura further teaches the washing of the shea nut meal can be carried out at a temperature of 10 to 80 °C (See column 3, lines 19-22) and



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that treatment with an alcohol solution can be carried out a temperature of 10 to 80 °C or by soaking the shea nut meal in the alcohol solution for a period of 30 minutes to overnight (See column 3, lines 30-39). Oura further teaches that the solution can be treated to 100 to 160 °C for a period of 10 to 60 minutes (See column 3, lines 40-45). Oura further teaches that the solution can be filtered under reduced pressure and after cooling the solution, the shea nut meal may be dried and/or ground (See column 3, lines 55-58). Oura further teaches that the shea nut meal treated by heating is present in a solution in an amount of up to 10% by weight, usually in a range of 0.5-5% by weight and may be used in a large amount (See column 5, lines 2-6). Oura further teaches that the coloring composition may be in the form of a powder, pellets, a slurry, an emulsion, an aqueous suspension or the like (See column 4, lines 46-54).

Vogel teaches that solid liquid separation process can be accomplished by filtration or centrifugation (See page 558). Vogel further teaches that evaporation is the removal of a solvent as a vapor from a solution or slurry and that the demanded of an evaporator is to concentrate a feed stream by removing a solvent which is vaporized in the evaporator and, for the greatest number of evaporator systems, the solvent is water and that the "bottoms" product is a concentrated solution, a thick liquor, or possibly a slurry and is most usually the desired and valuable product (See page 476).

The teachings of Oura, Noller and Vogel are set forth above and applied as before. Oura does not teach an incubation step is performed at a temperature of between 15 and 95 °C and over a period of between 10 minutes and 5 hours, nor does Oura teach removing solids by centrifugation, nor does Oura teach obtaining an extract

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containing at least 1 % by weight dry matter, nor does Oura teach further concentrating the shea nut meal by evaporation. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method as taught by Oura to provide the instantly claimed invention because at the time the invention was made, it was known within the art that upon heating the solution, the solution could be separated from the solids and that the shea nut meal solution could subsequently be dried. Therefore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a temperature and time period over which a solution is incubated, to pick and choose a method of obtaining a saponin-rich extract of shea nut meal by separating solids from a liquid solution, to pick and choose an amount of dry matter present in an extract and to pick and choose a suitable method for obtaining or drying (evaporating the solvent from) the shea nut meal extract, as clearly taught by Oura and Vogel. Furthermore, since centrifugation is a suitable alternative to filtration for separating solids from liquids and concentration by evaporation is a suitable method for drying or concentrating a solution, as was well known in the art at the time the invention was made, as clearly taught by Vogel, the claimed invention is no more than the routine optimization of a result effect variable.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the amount of time a solution is incubated, to pick and choose a method

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of obtaining a solution from solids, to pick and choose the amount of dry matter present in an extract and to pick and choose a method for drying or concentrating an extract) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

This rejection is maintained for reasons of record set forth in the paper mailed on 8 August 2006 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 8 November 2006.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues that the Examiner reiterates the teachings of Oura et al. discussed above and then makes another apparent misreading of Oura et al., stating that "Oura further teaches that the shea nut meal treated by heating is present in a solution in an amount of up to 10% by weight, usually in a range of 0.5-5% by weight and may be used in large amount (See column 5, lines 2-6)." Applicant further argues that Applicant does not understand the Examiner's remarks and that Column 5, lines 2-6 of

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Oura et al. discusses the use of the treated nut meal as a coloring additive in foods. Applicant further argues that the sentence containing the phrase "...up to 10% by weight..." in Oura et al. is teachings that one of ordinary skill can add up to 10% by weight of the treated nut meal to the food to color it and that it is not a description of the concentration of saponins in the extracted solution taught by Applicant. Applicant further argues that Vogel et al. for the general teaching that separating solids from liquids can be accomplished by means of evaporation, filtration or centrifugation, which is well known in the art, there is no mention of saponins or sapogenins in Vogel et al. Applicant further argues that Oura et al. do not teach an incubation step at a temperature between 15-95 °C for 10 minutes to 5 hours, nor do Oura et al. teach removing solids by centrifugation, or making an extract containing at least 1% by weight of dry matter. Applicant further argues that the Examiner states that Oura et al. also do not teach, "...further concentration the shea nut meal by evaporation" (see page 15 of the Office Action) and that is a misunderstanding of what is taught and claimed in Applicant's application. Applicant further argues that Applicant has previously pointed out in the present reponse with regard to the anticipation rejection, Applicant's teaching is not directed to concentrating shea nut meal and that Applicant teaches the aqueous extraction of saponins under alkaline conditions from the shea butter tree cake or nut meal. Applicant further teaches that as such, the Examiner's argument, that it would have been obvious to one of ordinary skill in the art to modify the process at the time the invention was made, it was known in the art that upon heating the solution, the solution could be separated from the solids and that the shea nut meal solution could be dried, is

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misdirected. Applicant further argues that Applicant is not making or claiming concentrated or dried shea nut butter and that the burden is on the Examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references (In re Deuel). Applicant further argues that only after that burden is met, must the Applicant come forward with arguments or evidence in rebuttal. Applicant further argues that to establish a case of *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art (See In re Royka). Applicant further argues that the Examiner has failed to establish a *prima facie* case of obviousnesses with regard to amended claims 1, 2 and 4-8, because Oura et al., in view of Noller and Vogel et al. do not teach each and every element of the claimed invention. Applicant further argues that Applicant claims a method for making an aqueous extract from shea butter tree nut meal or cake which is enriched in saponins under alkaline conditions and that the references alone, or together, do not teach Applicant's method. Applicant further argues that references cited only teach that shea nut meal can be heated and washed and used as a food additive and that there is no teaching or suggestion in any of the cited references for using shea butter tree nut meal as a starting material to extract saponins or the further processing of the extracted saponins into sapogenins. Applicant further argues that the Examiner has failed to provide any motivation for one of skill in the art to extract saponins from own specification and that Oura et al. are silent on saponins and the entire reference is directed to the use of the nut meal as a coloring additive for food. Applicant further argues that Vogel et al. is a general reference to extraction and separation techniques.

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Applicant further argues that the Examiner has not provided motivation to combine the cited references, and the references themselves fail to teach each and every element of Applicant's claimed invention.

However, this is not found persuasive because at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method as taught by Oura to provide the instantly claimed invention because at the time the invention was made, it was known within the art that upon heating the solution, the solution could be separated from the solids and that the shea nut meal solution could subsequently be dried. Therefore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a temperature and time period over which a solution is incubated, to pick and choose a method of obtaining a saponin-rich extract of shea nut meal by separating solids from a liquid solution, to pick and choose an amount of dry matter present in an extract and to pick and choose a suitable method for drying the shea nut meal extract, as clearly taught by Oura and Vogel. Furthermore, since centrifugation is a suitable alternative to filtration for separating solids from liquids and concentration by evaporation is a suitable method for drying a solution, as was well known in the art at the time the invention was made, as clearly taught by Vogel, the claimed invention is no more than the routine optimization of a result effect variable.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Applicant's alleged claiming of a method of aqueous extraction of saponins under alkaline conditions from shea butter tree cake or nut meal (See page 14, paragraph 4 of "Applicant Arguments/Remarks Made in an Amendment" filed on 8 November 2007) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Please note that Applicant is claiming a method of obtaining an aqueous extract obtained from shea nut meal that contains saponins, which is a completely different invention from a method of obtaining saponins from an aqueous extract of shea nut meal or a method of obtaining saponins from shea nut meal. Applicant appears to confuse these two methods throughout Applicant's arguments. Based upon Applicant's arguments, it appears that Applicant is meaning to direct the invention to a method of obtaining saponins from shea nut meal, however, the invention claimed by Applicant is drawn to a method of making an aqueous extract from shea nut meal (wherein the aqueous extract contains saponins).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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In response to Applicant's argument that Vogel et al. for the general teaching that separating solids from liquids can be accomplished by means of evaporation, filtration or centrifugation, which is well known in the art, there is no mention of saponins or sapogenins in Vogel et al., please note that the intention of this reference was to illustrate that any technique may be employed to separate a solid from a liquid. The Vogel reference was not intended to teach saponins or sapogenins, which is why it was combined with other references that did teach these elements of the invention to provide a *prima facie* obviousness rejection, wherein the method of separating a solid from a liquid is merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

In response to Applicant's argument that Applicant is not making or claiming concentrated or dried shea nut butter, please note that in claim 8, Applicant claims a step of concentrating and/or purifying the aqueous extract by evaporation of water and/or ultrafiltration and/or recrystallization, please note that concentration of a solvent usually provides a dried or concentrated product (even if the product is still in the form of an oil). Therefore, although the Examiner notes that the Examiner did not indicate that removing solvent was also regarded as a means of concentrating a solution, this was an oversight and was meant to be included with "drying" in the original rejection. Finally, the step claimed by Applicant in claim 8 recites a step of concentrating by evaporation of solvent, thereby indicating that Applicant is indeed claiming that the aqueous extract of shea nut butter is concentrated.



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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, because at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method as taught by Oura to provide the instantly claimed invention because at the time the invention was made, it was known within the art that upon heating the solution, the solution could be separated from the solids and that the shea nut meal solution could subsequently be dried. Therefore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a temperature and time period over which a solution is incubated, to pick and choose a method of obtaining a saponin-rich extract of shea nut meal by separating solids from a liquid solution, to pick and choose an amount of dry matter present in an extract and to pick and choose a suitable method for drying the shea nut meal extract, as clearly taught by Oura and Vogel. Furthermore, since centrifugation is a suitable alternative to filtration for separating solids from liquids and concentration by evaporation is a suitable method

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for concentrating a solution, as was well known in the art at the time the invention was made, as clearly taught by Vogel, the claimed invention is no more than the routine optimization of a result effect variable. Therefore, the Examiner has established a *prima facie* case of obviousness and that the burden is met by the Examiner to establish such a case. Please note that Applicant is claiming a method of making an aqueous extract of butter cake meal from shea butter tree. The method taught as taught by Oura also provides an aqueous extract of meal obtained from shea butter tree, which reads on Applicant's claimed invention. Finally, Oura teaches that the aqueous extract is used as a food coloring agent, however, this is merely an intended use and does not distinguish the method as taught by Oura in combination with Noller and Vogel, therefore, the Examiner has provided motivation to combine the cited references and the combined references teach each and every element of Applicant's claimed invention.

**No claims are allowed.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Amy L. Clark  
January 24, 2007

  
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PRIMARY EXAMINER